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# A study to assess drug related problems in patients with Cardiovascular Diseases in a tertiary care teaching hospital

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## ABSTRACT

**Back ground:** Drug related problems are common in hospitalized patients and may lead to increase hospital stay, health care cost and augment the risk of morbidity and mortality.
**Objective:** The aim of the study is to examine the nature and frequency of drug related problems, to minimize drug related problems and to improve therapeutic outcome by pharmaceutical care provided by clinical pharmacist.
**Methodology:** A prospective study was conducted in the cardiology department of a tertiary care hospital over a period of six months. Necessary demographic and clinical data was collected from the case records including drug history, other relevant details of the admitted patients and reviewed by the clinical pharmacist for drug related problems.
**Results:** A total of 280 patient case sheets were reviewed during the study period, out of which 244 drug related problems were identified. The most common drug related problem was found to be drug interactions (58.6%) followed by untreated indication (19.26%) and drug use without indication (15.57%). The most frequent suggestions provided by the intervening pharmacist were drug discontinuation (5.32%), addition of a new drug (5.32%) and change of dosage form (4.5%).
**Conclusion:** Drug related problems are common among medical ward patients. Routine participation of clinical pharmacist in clinical medical rounds facilitates the identification of drug related problems and the current study highlights the importance of pharmacist in a multidisciplinary team of reviewing drug therapy for identification and resolution of DRPs which helps in achieving better therapeutic outcomes and improved patient care.

**Keywords:** cardiovascular diseases, clinical pharmacist, dyslipidemia, drug related problem.

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## INTRODUCTION

Cardiovascular disease is a major public health problem and one of the leading causes of premature death throughout the world, and contributes substantially to increased health care costs. The most common underlying pathology expected to cause cardiovascular diseases is atherosclerosis. It is potentially a serious condition and one of the most common causes of cardiovascular diseases develops over many years and they are often fatal before any medical care can be given. The early identification and modification of risk factors has been shown to reduce mortality and morbidity in people with diagnosed or undiagnosed cardiovascular disease[1]. People with established cardiovascular disease have to give special care as they are at very high risk of recurrent events. Cardiovascular disease is usually seen in middle-aged or elderly men and women and it is expected that atherosclerosis is the main under pathology leading to coronary artery disease, cerebral artery disease and peripheral artery disease. Though several forms of therapy exist to prevent the coronary, cerebral and peripheral vascular events, decisions about whether to initiate specific preventive action, and with the degree of intensity, should be guided by estimation of the risk of any such vascular event. Management of major cardiovascular risk factors can be done through changes in the sedentary lifestyle and prophylactic drug therapies[2].

The presence of cardiovascular risk factors such as tobacco use, an unhealthy diet and physical inactivity (which together result in obesity), elevated blood pressure (hypertension), abnormal blood lipids (dyslipidemia) and elevated blood glucose (diabetes) and continuous exposure to them influences the progression of atherosclerosis. This

may result in unstable atherosclerotic plaques, narrowing of blood vessels and obstruction of blood flow to vital organs, such as the heart and the brain[3]. The clinical manifestations of these diseases include angina, myocardial infarction, transient cerebral ischemic attacks and stroke. Drug related problems may arise at all stages of the medication process from prescription to follow-up of treatment. Most of the problem usually occurs on administration, dispensing and during the patient's use of a medicinal product, but lack of proper follow-up and reassessment of medical treatment by the physician is also a major problem. A Drug related problem (DRP) is defined as, an any event or circumstance involving drug treatment that interferes or potentially interferes with the patient achieving an optimum outcome of medical care[4].

Increased number of medications, complexity of drug regimens and availability of new drug therapies potentially increase the risks of patient for iatrogenic adverse drug events in hospitals. This can lead to prolonged hospital stay and increased health care costs. So the injury or death that may occur as a result of drug related problems has to be evaluated so as to reduce the occurrence of similar events in future. Drug-related problems occur more frequently in hospitalized patients where multiple changes are being made in patient's medication regimens and lack of continuity of care may be accompanied. The most common problems associated with drug use are many and includes inappropriate medication prescribing, discrepancies between prescribed and actual regimens, poor adherence, drug interactions, inappropriate use, patients monitoring and inadequate surveillance for adverse effects etc. Drug related problems lead to substantial morbidity, mortality as well as increased health care expenditure which in turn affect the patient's quality of life. A medication-related problem is an event or circumstance involving medication therapy that actually or potentially interferes with an optimum outcome for a specific patient[5,6].

The main objective of medication use in any disease is to optimize drug therapy with minimum safety related problems within the frame work of pharmaceutical care plan. The goal of pharmaceutical care is to optimize the drug therapy, achieve positive clinical outcomes within realistic economic expenditures and improve patient's health related quality of life. Availability of new drug therapies and increased use of medications may potentially increase the risks for patients to iatrogenic adverse drug events in the hospitals. Iatrogenic adverse events are important for consideration because they not only prolong the hospital stay but also increase the health care.

**Aim**

To minimize drug related problems and to improve therapeutic outcomes by pharmaceutical care provided by clinical pharmacist.

**Objectives**

- To examine number and nature of drug related problems in patients with cardiovascular diseases and to demonstrate the role of pharmacist in ensuring safe and efficient use of medications in daily practice in the inpatient settings.
- To provide pharmaceutical care interventions based on the existing DRPS.

## MATERIALS AND METHODS

**Study site:**

Tertiary care Hospital, Bengaluru, Karnataka, India.

**Study design:**

This is a prospective and observational study.

**Study period:**

The study will be carried out for a period of six months.

**Study criteria:**

**Inclusive criteria**

- Patients admitted with cardiovascular diseases
- Patients of both sex and above 18yr old undergoing treatment on the cardiology inpatient wards of the hospital are included in the study.

**Exclusive criteria**

- Patients undergoing treatment less than one day of hospital stay are excluded from the study.
- Patient undergoing treatment on outpatient basis

**Source of data:**

The data were collected from treatment chart, laboratory report and patient medical records.

**Study procedure:**

It was a prospective observational study carried out for a period of 6 months in hospitalized cardiovascular patients admitted in the cardiology department. All the patients with cardiovascular diseases admitted in the cardiology department of both sex have been included in the study. All the cases were reviewed by the clinical pharmacists and those who met the study criteria were followed and drug therapy details were recorded in the suitable designed data collection form as per the need of the study. The classification includes drug use without indication, untreated indication, improper drug selection, over dose, sub therapeutic dose, adverse drug reactions, and drug interactions. The acceptance level for each intervention was also recorded as either accepted or nor accepted. Similarly, whether or not any change in drug therapy was also noted.

**Data collection form:**

The data collection form was developed by referring available literatures and objective requirements. It includes patient demographics, final diagnosis chart, past medical history, treatment chart, laboratory results.

**Documentation:**

The data collected from the patients was documented, for further analysis. Microsoft excel software is used for statically analysis.

## RESULTS

A prospective observational study was conducted over a period of 6 months in cardiology department at BGS global hospital, Bengaluru, Karnataka, India. During the study 280 patients were enrolled.

**Table 1: Gender distribution**

| Gender | No. of patients | Percentage (%) |
|---|---|---|
| Male | 214 | 76.4% |
| Female | 66 | 23.5% |

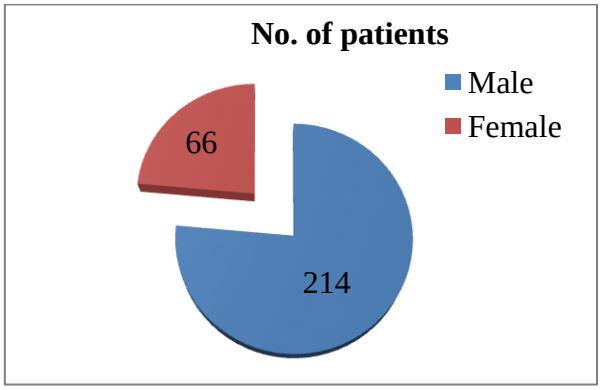


**Figure 1: Chart representing gender distribution**

The total number of subjects enrolled in this study was280, out of which 214 (76.4%) were found to be male and 66 (23.5%) were found to be female, as represented in above diagram.

**Table 2: Distribution of patients according to age group**

| Age group (years) | No of patient(n=91) | Percentage (%) |
|---|---|---|
| 21-30 | 8 | 2.85% |
| 31-40 | 20 | 7.14% |
| 41-50 | 60 | 21.42% |
| 51-60 | 78 | 27.85% |
| 61-70 | 88 | 31.42% |
| 71-80 | 22 | 7.85% |
| >81 | 4 | 1.42% |

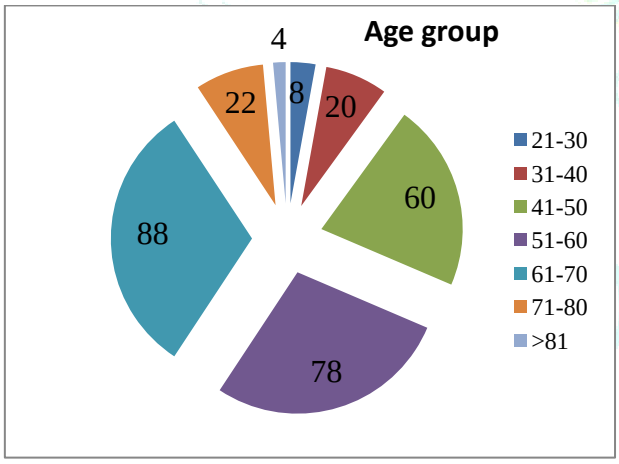


**Figure 2: Distribution according to age (in years) group**

Out of the 280 subjects, 8 (2.5%) were under the age group of 21-30 years, 20(7.14%) were under the age group of 31-40, 60 (21.42%) were under the age group of 41-50, 78 (27.85%) were under the age group of 51-60, 88 (31.42%) under the age group of 61-70, 22 (7.85%)under the age group of 71-80, 4 (1.42%) under the age group of >81 as represented in above diagram.

**Table 3: Distribution of patients based on length of the stay**

| Length of stay | No. of patients (n=280) | Percentage (%) |
|---|---|---|
| 1-3days | 152 | 54.2 |
| 4-6days | 105 | 37.5 |
| 7-9days | 21 | 7.5 |
| >10days | 2 | 0.71 |

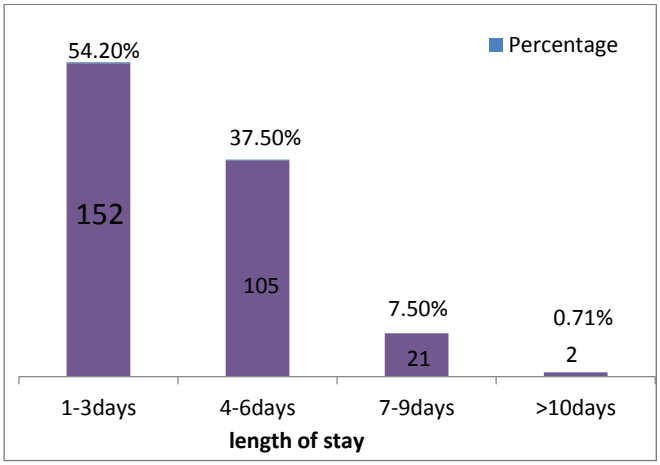


**Figure 3: Distribution of patients based on length of the stay**

Out of the total number of subjects, 152 patients were stayed for 1-3days, 105 patients were stayed for 4-6days, 21 patients for 7-9 days and 2 patients for more than 10 days as represented above.

**Table 4: Distribution of the patients according to the no. of medications**

| No. of medications | No. of patients | Percentage (%) |
|---|---|---|
| 1-5 | 29 | 10.35% |
| 6-10 | 112 | 40.0% |
| >10 | 139 | 49.64% |

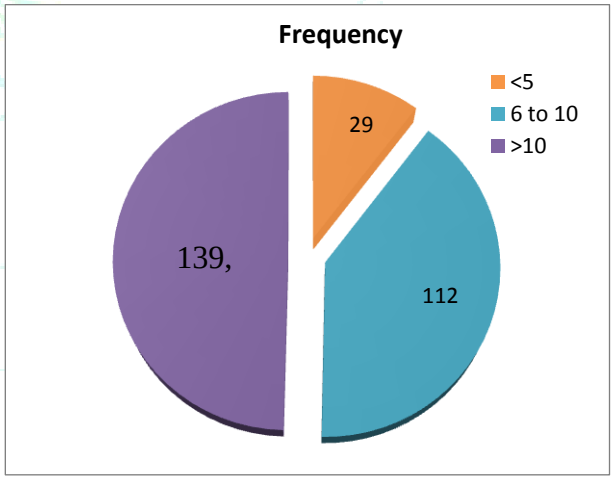


**Figure 4: Distribution of patients according to no. of medications**

Out of 280 patients, 29 patients received <5medication, 112 patients received 6-10 medications, 139 patients received >10 medications.

**Table 5: Comorbidities of patients in cardiology department**

| Comorbidity | Number | Percentage |
|---|---|---|
| 0 Comorbidity | 26 | 9.20% |
| 1 Comorbidity | 135 | 48.20% |
| 2 Comorbidities | 84 | 30% |
| 3 Comorbidities | 28 | 10% |
| 4 Comorbidities | 6 | 2.10% |

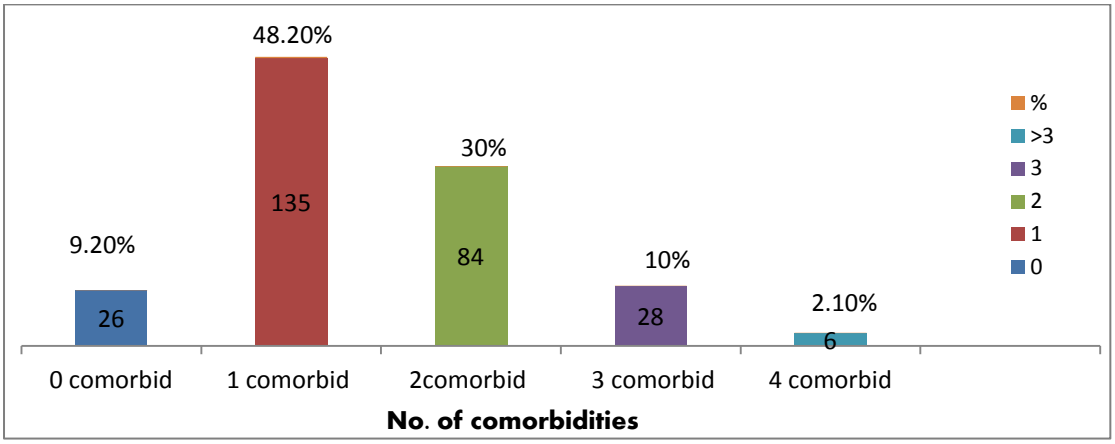


**Figure 5: Comorbidities of patients in cardiology department**

Out of the total number of subjects, 9.20% patients have 0 comorbidity, 48.20% patients have 1 comorbidity, 30% patients have 2 comorbidities, 10% patients have 3 comorbidities and 2.10% patients have 4 comorbidities.

**Table 6: Patients with one comorbid condition**

| One-comorbid condition | Number | Percentage |
|---|---|---|
| Hypertension | 38 | 13.57% |
| Diabetes Mellitus | 32 | 11.40% |
| Anemia | 2 | 0.71% |
| Deep vein thrombosis | 2 | 0.71% |
| Bronchial Asthma | 2 | 0.71% |

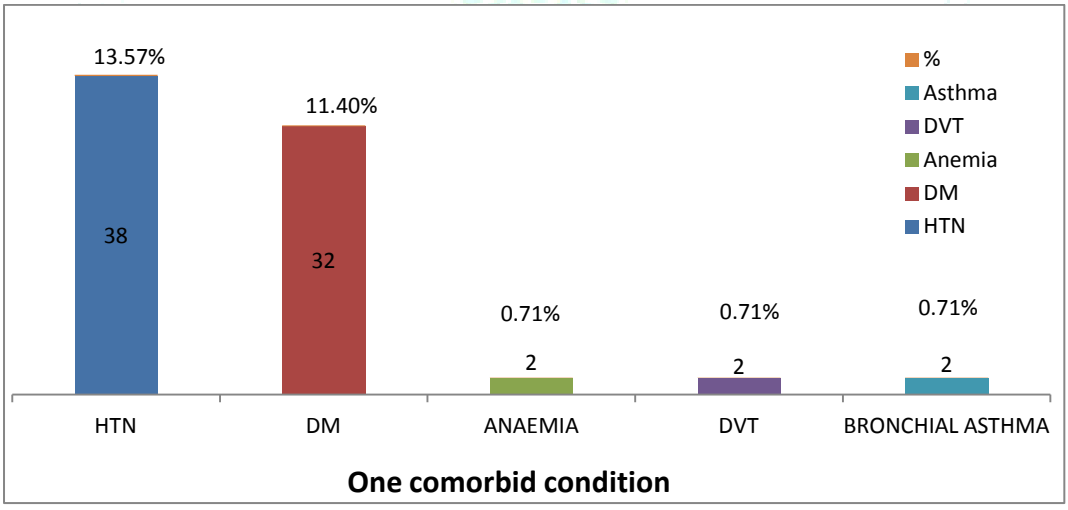


**Figure 6: Patients with one comorbid condition**

Out of the total number of subjects, 13.57% patients have hypertension, 11.40% patients with diabetes mellitus, 0.71% patients with anemia, 0.71% patients with deep vein thrombosis and 0.71% patients with bronchial asthma.

**Table 7: patients with two comorbid conditions**

| Two comorbidity condition | Number | Percentage |
|---|---|---|
| DM+HTN | 33 | 11.78% |
| HTN+RHD | 2 | 0.71% |
| HTN+DVT | 2 | 0.71% |

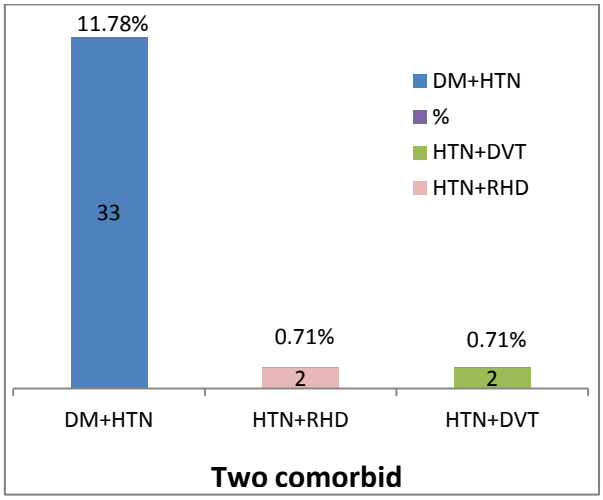


**Figure 7: Patients with two comorbid conditions**

Out of the total number of subjects, 11.78% patients were diagnosed with diabetes mellitus + hypertension, 0.71% patients were diagnosed with hypertension + rheumatic heart disease and 0.71% patients were diagnosed with hypertension + deep vein thrombosis.

**Table 8: Patients with three comorbid conditions**

| Three comorbid condition | Number | Percentage |
|---|---|---|
| DM + HTN + Hypothyroidism | 3 | 1.07% |
| DM + HTN + Anemia | 2 | 0.71% |

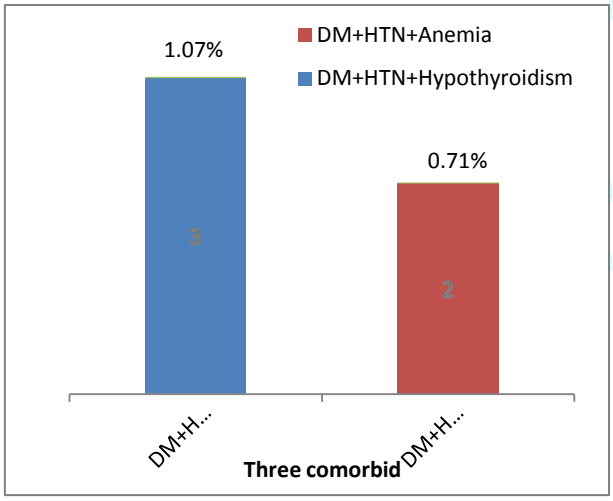


**Figure 8: Patients with three comorbid conditions**

Out of the total number of subjects, 1.07% patients were diagnosed with diabetes mellitus + hypertension + hypothyroidism, 0.71% patients were diagnosed with diabetes mellitus + hypertension + anemia.

**Table 9: Drug use without indication**

| Drug | Number | Percentage |
|---|---|---|
| Emeset | 16 | 25.30% |
| Alprazolam | 11 | 17.40% |
| Duphalac | 8 | 12.60% |
| Duolin | 3 | 4.70% |

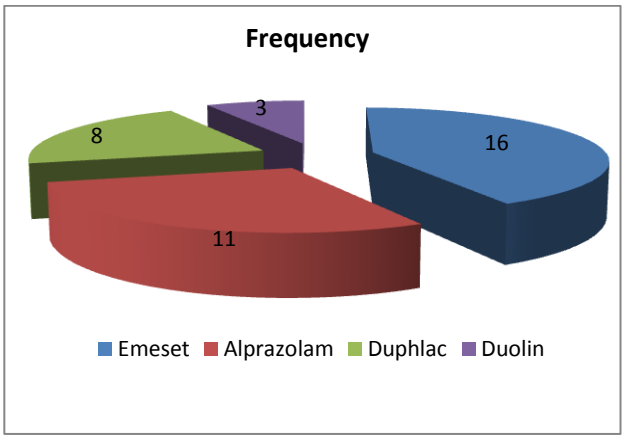


**Figure 9: Drug use without indication**

Few drugs often used without indication include emeset 25.30%, alprazolam 17.40%, duphalac 12.60% and duolin 4.70%.

**Table 10: Untreated indication**

| Condition | Number | Percentage |
|---|---|---|
| Dyspnea | 26 | 49.0% |
| Anemia | 13 | 13.20% |
| Cough | 5 | 9.40% |
| Constipation | 3 | 5.60% |

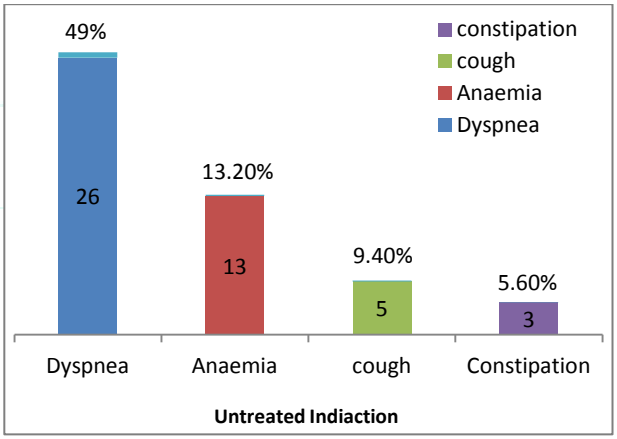


**Figure 10: Untreated indication**

Out of the total number of subjects, the some of the untreated indications are dyspnea (49%), anemia (13.2%), cough (9.40%) and constipation (5.60%).

**Table 11: Adverse drug reactions**

| Class | Drug | ADR | No. of patients | Suggestion given and taken | Suggestion given not taken | Neither given nor taken |
|---|---|---|---|---|---|---|
| Anti-diabetic | Insulin | Hypoglycemia | 4 | - | - | 4 |
| Diuretic | Furosemide | Hypokalemia | 5 | 3 | 2 | - |
| Statins | Atorvastatin | Insomnia | 4 | - | - | 4 |
| Beta blocker | Carvedilol | Cough | 3 | 3 | - | - |

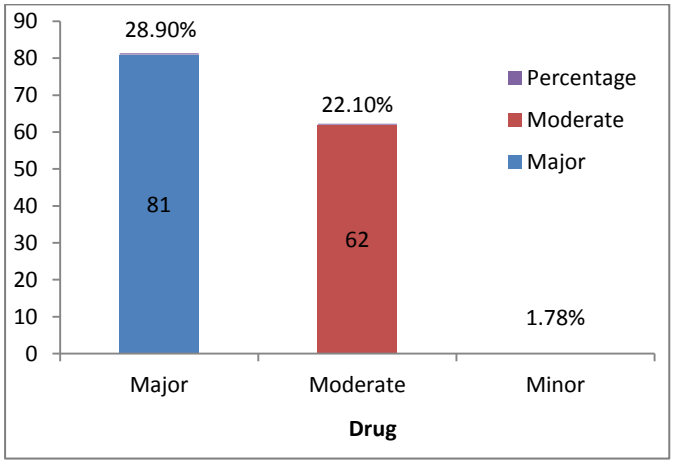


**Figure 11: Drug interactions**

Out of the total number of subjects, we found 28.90% major drug interactions (81), 22.10% moderate drug interactions (62) and 1.78% minor drug interactions (5) and these are theoretically observed interventions.

**Table 12: Frequently occurring major DIs**

| Major interactions | Effect | Frequency |
|---|---|---|
| Clopidogrel+aspirin | Increased risk of bleeding | 195 |
| Heparin+aspirin | Increased risk of bleeding | 183 |
| Clopidogrel+aspirin | Increased risk of bleeding | 145 |
| Aspirin+furosemide | Reduced furosemide effect | 71 |
| Aspirin+spironolactone | Reduced diuretic effect | 39 |
| Aspirin+metformin | Increased risk of hypoglycemia | 27 |
| Aspirin+tirofiban | Increased risk of bleeding | 26 |
| Aspirin+ticagrelor | Increased risk of bleeding | 25 |
| Aspirin+insulin | Increased risk of hypoglycemia | 25 |
| Amlodipine+clopidogrel | Decreased anti-platelet effect | 24 |
| Digoxin+aspirin | Increased risk of bleeding | 23 |

Out of 280 patients, 195 patients were developed increased risk of bleeding with clopidogrel+aspirin and 23 patients were developed with increased risk of bleeding with digoxin+aspirin.

**Table 13: Frequently occurring moderate interactions**

| Moderate interactions | Effect | Frequency |
|---|---|---|
| Clopidogrel+atorvastatin | Decreased effect of clopidogrel | 192 |
| Aspirin+metformin | Increased BP | 69 |
| Ranolazine+atorvastatin | Increased risk of myopathy | 61 |
| Carvedilol+aspirin | Increased risk of BP | 38 |
| Heparin+ticagrelor | Increased risk of bleeding | 26 |
| Telmisartan+spironolactone | Increased risk of hyperkalemia | 19 |

Out of 280 patients 192 patients showed decreased effect of clopidogrel with clopidogrel+atorvastatin and 19 patients were developed increased with telmisartan+spironolactone.

**Table 14: Types of drug related problems**

| Types of DRPs | Number | Percentage (%) |
|---|---|---|
| Drug use without indication | 38 | 15.57 |
| Sub therapeutic dose | 0 | 0 |
| Untreated indication | 47 | 19.26 |
| Failure to receive drug | 0 | 0 |
| Adverse drug reaction | 16 | 6.55 |
| Overdose | 0 | 0 |
| DI | 143 | 58.6 |
| Improper drug selection | 0 | 0 |

Among 280 patients followed during the study period, a total of 244 DRPs (99.98%) were identified. Out of 58.6% were found to be drug interactions (143), 19.26% were found to be untreated indication (47), 15.57% were found to be drug use without indication (38) and 6.55% were found to be adverse drug reaction (16).

**Table 15: Types of pharmacist interventions to prevent DRPs**

| Drug choice | Number | Total |
|---|---|---|
| Drug discontinuation | 13 | 5.32% |
| Addition of a new drug | 13 | 5.32% |
| Change of dosage form | 11 | 4.5% |
| Decrease the dose | 10 | 4.09% |

Types of pharmacist interventions given to prevent DRPs were found to be 5.32% drug discontinuation (13), 5.32% addition of a new drug (13), 4.5% change of dosage form (11) and 4.09% decrease the dose (10).

**Table 16: Results of pharmacist interventions**

| Recommendations | Result |
|---|---|
| Suggestion given and taken | 42 |
| Suggestion given not taken | 23 |
| Neither given nor taken | 215 |

Outcomes of the recommendation concerning drug related problems are suggestion given and taken 42, suggestion given not taken 23 and neither given nor taken 215.

## DISCUSSION

Among 280 patients followed during the study period, a total of 244 DRPs were identified. In the total population 214 were male patients and 66 were female patients. Male population was more due to increased medication use because of their multiple comorbid conditions and also possibility of various risk factors like smoking, alcoholism and sedentary life style compared to female population. The age group was categorized in to four groups such as 21-40, 41-60, 61-80, and more than 80. The incidence was DRPs was high (49.3%) in patients aged between 41-60 years. Among the number of drugs, patients receiving more than 6 drugs have more drug related problems. In the study 40% of the patients received 6-10drugs, 49% of the patients received >10 drugs and 10.3% patients received <5drugs.

These findings were similar to the study carried out by celin et al.[7], which showed that 50% of overall population took more than 10 medications and developed DRP's. Patients were categorized according to the number of comorbid conditions in which 135 patients have single comorbidity, 84 have two comorbidities and 28 has three comorbidities. This observation was similar to the study conducted by Seuma J et al.[7], of which 48.20% of the population has at least one comorbid condition.

This indicates that special attention should be done in such group of patients where regular review of drug therapy might help potentially to decrease the drug related problem. Drug interactions were the most common drug related problem observed in the study (58.6%) followed by untreated indication (19.26%) and drug use of all the drug interactions 28.90% were major drug interactions (81), without indication (15.57%), Adverse drug reactions (6.55%), overdose (4.09%). 22.10% were moderate interactions (62) and 1.78% were minor interactions (5).

This observation was in contrast with the study conducted by Celin et al.[7], in which potential drug interaction was found to be high. In the present study the therapeutic agents most commonly involved in drug interactions were anti-platelet agents, anti-hypertensives and GI drugs.

In our study the untreated indication was found to be 19.26% and some of the untreated indications are dyspnea (49%), anemia (13.2%), cough (9.4%), and constipation (5.6%). This was found to be similar to the observational study conducted by Celin et al.[7], where 7% of the untreated indication account for the total drug related problems. In this study, drug use without indication accounts for 15.57%. Few drugs often used without indication include ondansetron (25.30%), alprazolam (17.40%), duphalac (12.60%), duolin (4.70%). In some cases, anti-emetics have been prescribed for vomiting but it has been continued even after the vomiting has stopped.

These study findings are in contrast with the study carried out by Alagiriswami et al.[8], which shows that drug use without indication accounts for 18% of total DRP's respectively. Adverse drug reactions can cause a significant financial burden to the health care system. In the study we observed 6.55% of the adverse drug reactions are hypoglycemia due to insulin in diabetic patients, hypokalemia due to furosemide, insomnia due to atorvastatin, and cough due to carvedilol.

Types of pharmacist's intervention were drug discontinuation and addition of new drug (5.32%), change of dosage form (4.5%) and decrease in the dosage form (4.09%). These findings were similar to the study carried out by Rani Reema Abraham[2] and Alagiriswami et al.[8], where drug discontinuation, addition of a new drug, change of dosage form were the interventions provided by the clinical pharmacists. The acceptance of pharmacist's interventions was found to be high i.e. 42 cases. 23 recommendations were accepted but the therapy was not changed perhaps due to lack of proper information which needs to strengthen the suggestions provided or the suggestions provided were thought to be insignificant. In 215 cases the suggestions were neither suggested nor the drug therapy changed.

This was similar to the study carried out by Reema Abraham[2], where outcomes of the pharmacist interventions were divided as suggestion accepted and taken, suggestion accepted but therapy not changed and neither suggestion nor therapy changed. This indicates that a clinical pharmacist can contribute to better patient care if involved in the health care team. The overall findings from our study was that pharmacists could identify some drug related problems, prompt and proper interventions will help in achieving better patient care that can lead to improve the quality of care and drug therapy.

## CONCLUSION

The present study demonstrated that patients with cardiovascular diseases suffer from large number of drug related problems that may be solved or prevented by pharmacist interventions. Out 0f 280 patients a total of 244 drug related problems were identified. The most frequently identified drug related problems were drug interactions (58.6%) followed by untreated indications (19.26%) and drug use without indications (15.57%). Policy makers should consider implementing systematic medication reviews on regular basis to achieve and maintain high quality drug treatment in general hospitals.

Types of pharmacist interventions were drug discontinuation, addition of new drugs, change of dosage form and decrease in the dosage form. The acceptance of pharmacist's interventions was found to be in 42 cases. So review of the patient's drug therapy by clinical pharmacist can positively influence the patient's outcomes and quality of care. In the present study drug related problems were identified, reported and relevant interventions were made accordingly thereby improved therapeutic outcome and patient quality of life.

The present study highlights the fact that clinical pharmacist can play a very important role in the health care management by rationalizing and optimizing the drug therapy in achieving better quality of life. This study strongly suggested that, there are more drug related problems in cardiovascular patients. Hence this study clearly showed that the pharmaceutical care is very much essential in cardiovascular patients.

## ACKNOWLEDGEMENT

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## CONFLICTS OF INTEREST

The author declares that there is no conflict of interest to disclose.

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